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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,117	10/22/2003	Peter M. Allred	7678.816	6558

22913 7590 11/16/2004

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EXAMINER	
O CONNOR, CARY E	
ART UNIT	**PAPER NUMBER**
3732	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,117	ALLRED ET AL	
	Examiner	Art Unit	
	Cary E. O'Connor	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *56 and 57* is/are allowed.

6)☒ Claim(s) *1-55 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the limitation "said dental desensitizing device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-15, 17-29, 31-35, 37-42, 44, 49-55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382). Wiesel shows an article of manufacture comprising a shaped dental bleaching composition having a tray-like configuration comprising front side wall, a rear side wall, and a trough between the front and rear side wall (see Figs. 2 and 3). The composition further comprises an adhesive layer 12 comprising a substantially solid adhesive composition (paragraph 0030). The composition also comprises a bleaching

gel 16, adjacent to an inner surface of the adhesive layer, comprising at least one dental bleaching agent (30 to 35% hydrogen peroxide), a tackifying agent (carbopol) and a gel carrier. The adhesive disclosed by Wiesel does not have increased adhesiveness to teeth when moistened. Chang shows an article of manufacture for bleaching teeth comprising an adhesive layer that provides substantial adhesive strength when hydrated by water. This type of adhesive does not stick to the hands or face during application, thereby making the article easier to handle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the adhesive of Wiesel with that taught by Chang, because the adhesive of Chang is easier to handle. As to claims 3, 4, 49 and 50, since the article of Wiesel is in sheet form it inherently has a longitudinal curvature (i.e. zero curvature) less than the curvature of the dental arch prior to use. As to claims 5, 6 and 8, note that a portion of the trough of Wiesel has an approximate U-shaped (or rectangular) cross section, as shown in Figs. 2 and 3, and would inherently form an approximate V-shape cross section when applied to the front teeth. As to claim 7, since a portion of the trough of Wiesel has an approximate U-shaped cross section, a portion of that cross-section is L-shaped. As to claim 11, Figures 2 and 3 show the bleaching composition 16 sized and configured so as to approximately terminate near a persons gingival margin. As to claims 12, 13 and 51, note paragraph 0041 of Chang. As to claims 14 and 15, note paragraph 0071 of Chang which discloses that the tooth adhesion agent having a concentration of about 20% by weight of the adhesive composition. As to claim 16, Chang does not disclose that the adhesion agent has a concentration in a range of about 40% to about 75% by

weight of the adhesive composition. At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the adhesive composition having the adhesive agent in the range of 40% to about 75% by weight because applicant has not disclosed that this range of concentration provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the concentration in the range claimed by applicant. As to claim 17, note that the adhesive composition of Chang may include a humectant (glycerin, see paragraph 0067). As to claims 18-20, neither Wiesel nor Chang disclose the thickness of the adhesive layer. At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the adhesive layer with a thickness in the range of .01 to about 3 mm because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant. As to claims 21, 22, 52 and 53, note that Wiesel discloses the addition of therapeutic medicaments or agents for treating sensitive teeth (paragraph 0045). As to claims 23-25, note the concentration of bleaching agent disclosed by Wiesel in paragraph 0034. As to claims 27-29, 31, 37, 39, 41, 42 and 44, note the flexible barrier layer 20 of Wiesel that may be formed of polyolefin or polyurethane (paragraph 0037). As to claims 32-33, Wiesel discloses the thickness of the barrier layer as being 30 mil (paragraph 37). At the time the invention was made, it would have

been obvious matter of design choice to a person of ordinary skill in the art to form the barrier layer with a thickness in the range of 0.025 mm to about 1.5 mm because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant. As to claim 34, note that Chang discloses a pouch for storage in paragraph 0062. As to claims 35 and 54, it is well known to provide a plurality of bleaching articles in a kit for use on multiple days. As to claims 38 and 55, note the method of use disclosed by Wiesel in paragraphs 0039 and 0040. As to claims 58-60, note that the adhesive of Wiesel is freeze-dried inherently removing at least a portion of the solvent.

Claims 2, 45, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claims 1 and 39 above, and further in view of Schwartz (6,089,869). The article of manufacture of Wiesel as modified by Chang is not initially horseshoe shaped prior to use. Schwartz shows a dental bleaching tray that is pre-formed in a horseshoe shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the article of Wiesel as modified by Chang in a horseshoe shape prior to use, in view of Schwartz, so that the article has a more customized fit thereby making it more effective.

Claims 30 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claims

29 and 42 above, and further in view of Sagel et al (2002/0018754). Wiesel does not disclose that the polyolefin comprises at least one of polyethylene, high density polyethylene, low density polyethylene, ultra-low density polyethylene, polypropylene, or polytetrafluoroethylene. Sagel shows an article of manufacture comprising a barrier layer made of polyethylene or polytetrafluoroethylene (paragraph 0038). These materials are compatible with the bleaching agents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use polyethylene or polytetrafluoroethylene as the barrier layer in Wiesel, in view of Sagel, because these materials are compatible with the bleaching agents.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesel (2002/0081555) in view of Chang et al 2003/0194382) as applied to claim 35 above, and further in view of Andreiko (5,752,826). Neither Wiesel nor Chang disclose that a plurality of dental bleaching compositions are stacked and interested together. Andreiko shows a single use dental impression tray and discloses that a plurality of the trays may be stacked together for easy storage (column 8, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the articles of Wiesel as modified by Chang in a stacked condition, in view of Andreiko, for ease of storage.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-35, 37-44, 47, 49-55, 58-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 2, 5-35, 39-46, 53-57 of copending Application No. 10/728,525 in view of Wiesel (2002/0081555). The claims of the copending application do not specify that the article of manufacture is in a tray like configuration as claimed in claims 1 and 39 of the instant application. Wiesel shows a dental bleaching product that is in the form of a tray when positioned on the teeth. It would have been obvious to form the article of the copending claims so that it may form a tray like structure when placed on the teeth, in view of Wiesel, so that the entire surface of the teeth may be exposed to the treatment gel.

Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/728,525 in view of Wiesel, as applied to claim 35 above, and further in view of Andreiko (5,752,826). The copending claim does not set forth that a plurality of dental bleaching compositions are stacked and interested together. Andreiko shows a single use dental impression tray and discloses that a plurality of the trays may be

stacked together for easy storage (column 8, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the articles of the copending claim as modified Wiesel in a stacked condition, in view of Andreiko, for ease of storage.

Claims 45, 46 and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/728,525 in view of Wiesel, as applied to claim 35 above, and further in view of Schwartz (6,089,869). The article of manufacture of the copending claim is not initially horseshoe shaped prior to use. Schwartz shows a dental bleaching tray that is pre-formed in a horseshoe shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the article of the copending claim as modified Wiesel in a horseshoe shape prior to use, in view of Schwartz, so that the article has a more customized fit thereby making it more effective.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

Claims 56 and 57 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 571-272-4715. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cary E. O'Connor
Primary Examiner
Art Unit 3732

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